

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
May 24, 2012

AGENDA

The committee will discuss new drug application (NDA) 202737, for tafamidis meglumine capsules, proposed trade name VYNDAQEL, submitted by FoldRx Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc. The proposed indication is for the treatment of transthyretin (TTR) familial amyloid polyneuropathy.

8:30 a.m.	Call to Order and Introduction of Committee	Nathan B. Fountain, M.D. Acting Chair, PCNS
8:40 a.m.	Conflict of Interest Statement	Glendolynn S. Johnson, Pharm.D. Designated Federal Officer, PCNS
8:45 a.m.	FDA Introductory Remarks	Russell Katz, M.D. Director Division of Neurology Products (DNP) Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA
9:00 a.m.	SPONSOR PRESENTATIONS	
	Introduction	Clare Kahn Vice President Worldwide Regulatory Strategy Specialty Care, Pfizer
	Disease Background and Treatment Paradigm	Steven R. Zeldenrust, M.D., Ph.D. Assistant Professor of Medicine Mayo Clinic Rochester, MN
	Tafamidis MOA and Clinical Pharmacology	Jeffery Kelly, Ph.D. Lita Annenberg Hazen Professor of Chemistry Scripps Research Institute La Jolla, CA
	Clinical Endpoints in TTR-FAP	Roy Freeman, M.D. Professor of Neurology Director, Center for Autonomic and Peripheral Nerve Disorders Harvard Medical School Boston, MA

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AGENDA (cont.)

Tafamidis Efficacy and Safety

Donna Grogan, M.D.

Medical Consultant

Former Chief Medical Officer, FoldRx (a wholly owned subsidiary of Pfizer, Inc.)

TTR-FAP Clinical Perspective

Teresa Coelho, M.D.

Largo Prof. Abel Salazar

Hospital Geral de Santo Antonio

Porto, Portugal

Tafamidis Benefit:Risk Assessment

Ilise Lombardo, M.D.

Senior Director, Medicines Development Group
Pfizer, Inc.

10:30 a.m. Clarifying Questions

10:45 a.m. **BREAK**

11:00 a.m. **FDA PRESENTATION**

Tafamidis in Transthyretin Amyloid
Polyneuropathy

Ronald Farkas, M.D., Ph.D.

Clinical Team Leader, DNP

ODE-I, OND, CDER, FDA

11:45 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee
Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee
Discussion

5:00 p.m. **ADJOURNMENT**